

Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes

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- **FDA cites 40 retailers for violations related to youth sales of JUUL e-cigarettes**
- **Agency announces a new blitz of retail establishments targeting youth sale violations**
- **Agency takes new action to examine youth appeal of JUUL**
- **Agency takes steps to foreclose online sales of JUUL to minors**
- **These are the first steps in a new effort aimed at stopping youth use of e-cigarettes**

Protecting our nation's youth from the dangers of tobacco products is among the most important responsibilities of the U.S. Food and Drug Administration – and it's an obligation I take personally. We recognize that if the FDA is to end the tragic cycle of successive generations of nicotine and tobacco addiction, we must take every opportunity to disrupt that process where it starts: youth access to and use of tobacco products.

That's why, as part of our [comprehensive plan](#) announced in July, we're pursuing a policy to prevent future generations from becoming addicted in the first place by rendering cigarettes minimally or non-addictive. A key part of that plan was establishing the foundational framework for regulating non-combustible tobacco products for adults, like e-cigarettes.

But as we work to keep kids from making the deadly progression from experimentation to regular cigarette use, it's imperative that we also make sure children and teenagers aren't getting hooked on more novel nicotine-delivery products.

Today, we're announcing several new actions and efforts aimed at doing just that as the first steps in a new Youth Tobacco Prevention Plan focused on stopping youth use of tobacco products, and in particular, e-cigarettes.

The troubling reality is that electronic nicotine delivery systems (ENDS) such as e-cigarettes have become wildly popular with kids. We understand, by all accounts, many of them may be using products that closely resemble a USB flash drive, have high levels of nicotine and emissions that are hard to see. These characteristics may facilitate youth use, by making the products more attractive to children and teens.

These products are also more difficult for parents and teachers to recognize or detect. Several of these products fall under the JUUL brand, but other brands, such as myblu and KandyPens, that have similar characteristics are emerging. In some cases, our kids are trying these products and liking them without even knowing they contain nicotine. And that's a problem, because as we know the nicotine in these products can rewire an

adolescent's brain, leading to years of addiction. For this reason, the FDA must – and will – move quickly to reverse these disturbing trends, and, in particular, address the surging youth uptake of JUUL and other products.

To address all of these concerns, the FDA is announcing a series of new enforcement and regulatory steps.

First, we're announcing that the FDA has been conducting a large-scale, undercover nationwide blitz to crack down on the sale of e-cigarettes – specifically JUUL products – to minors at both brick-and-mortar and online retailers. The blitz, which started April 6 and will continue to the end of the month, has already revealed numerous violations of the law.

The illegal sale of these JUUL products to minors is concerning. In fact, just since the beginning of March, FDA compliance checks have uncovered 40 violations for illegal sales of JUUL products to youth. The FDA has issued 40 warning letters for those violations, which we are also announcing today. This includes warning letters that are the result of the blitz. Others are a result of our sustained enforcement efforts to reduce tobacco product sales to minors. And we anticipate taking many more similar actions as a result of the ongoing blitz and our focus on enforcement related to youth access.

We'll hold retailers accountable for continued violations. Let me be clear to retailers. This blitz, and resulting actions, should serve as notice that we will not tolerate the sale of any tobacco products to youth.

This isn't the first time we've taken action against retailers for selling these e-cigarettes and other tobacco products to minors, and it won't be the last. In fact, the FDA has conducted 908,280 inspections of retail establishments that sell tobacco products, issued 70,350 warning letters to retailers for violating the law and initiated about 17,000 civil money penalty cases. We have also issued more than 110 No-Tobacco-Sale Order Complaints, which can result in retailers being prohibited from even selling tobacco products for specified periods of time.

It's clear there's a need for strong federal enforcement of these important youth access restrictions and we'll continue to hold retailers accountable by vigorously enforcing the law with the help of our state partners. Today's action should serve to put retailers on notice to stop selling products to minors.

Second, as part of this effort, we also recently contacted eBay to raise concerns over several listings for JUUL products on its website. We're thankful for eBay's swift action to remove the listings and voluntarily implement new measures to prevent new listings from being posted to the web retailer's site. Our overarching goal – one we hope everyone shares – is to make sure JUUL, and any other e-cigarettes or tobacco products, aren't getting into kids' hands in the first place.

Third, we're also taking additional steps to contact the manufacturers directly, and hold them accountable. We need to examine all the available information to understand why kids are finding these products so appealing – and address it.

That's why today, the FDA also sent an official request for information directly to JUUL Labs, requiring the company to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of these products. The information we're requesting includes: documents related to product marketing; research on the health, toxicological, behavioral or physiologic effects of the products, including youth initiation and use; whether certain product design features, ingredients or specifications appeal to different age groups; and youth-related adverse events and consumer complaints associated with the products. We don't yet fully understand why these products are so popular among youth. But it's imperative that we figure it out, and fast. These documents may help us get there.

We plan to issue additional letters to other manufacturers of products that raise similar concerns about youth use. If these companies, including JUUL, don't comply with our requests, they will be in violation of the law and subject to enforcement.

Fourth, we are planning additional enforcement actions focused on companies that we think are marketing products in ways that are misleading to kids. I will have more to say on this in the coming weeks.

These actions are just the first in a series of efforts we're pursuing as part of our newly formed Youth Tobacco Prevention Plan. We will announce additional steps in the coming weeks and months. And I hope that this sends a clear message to all tobacco product manufacturers and retailers that the FDA is taking on this issue with urgency, and if kids are flocking to your product or you're illegally selling these products to kids, you're on the agency's radar.

We appreciate that JUUL Labs has already expressed recognition of this problem and has reached out to the FDA and other stakeholders to discuss these concerns. But we must all recognize that more needs to be done. As we've said before, there is no acceptable number of children using tobacco products. We share the belief that these products should never be marketed to, sold to, or used by kids – and we need to make every effort to prevent kids from getting hooked on nicotine. This responsibility falls not only to the FDA, but also the companies making these products, the retailers selling them, and the online venues that help to fuel the teen popularity of, and access to, these products.

Finally, as we pursue additional steps to keep kids from using tobacco products, we're also continuing to invest in our compelling, science-based campaigns to educate youth about the dangers of all tobacco products including e-cigarettes.

Last fall, the first content from our youth e-cigarette prevention campaign – an ad showing youth using a USB-like tobacco product – launched online. A full-scale e-cigarette prevention effort under "The Real Cost" brand umbrella is planned for a September launch.

We're also exploring clear and meaningful measures to make tobacco products less toxic, appealing and addictive with an intense focus on youth. Specifically, as part of our comprehensive plan, we intend to pursue product standards and other regulations for electronic nicotine delivery systems, such as e-cigarettes, to address known hazards and concerns, including exploding batteries and accidental ingestion. Ultimately, our work on tobacco and nicotine regulation is aimed at achieving the greatest public health benefit.

Make no mistake. We see the possibility for ENDS products like e-cigarettes and other novel forms of nicotine-delivery to provide a potentially less harmful alternative for currently addicted individual adult smokers who still want to get access to satisfying levels of nicotine without many of the harmful effects that come with the combustion of tobacco. But we've got to step in to protect our kids.

As the FDA considers regulating nicotine levels in cigarettes to render combustible cigarettes minimally or non-addictive, products such as e-cigarettes may offer a potentially lower risk alternative for individual adult smokers. These ENDS products will still need to be put through an appropriate series of regulatory gates by the FDA. But the viability of these products is severely undermined if those products entice youth to start using tobacco and nicotine.

The youth-focused steps we're taking are consistent with our responsibility to protect kids and significantly reduce tobacco-related disease and death, and I intend to do everything within my power to fulfill that duty.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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